

NOV 26 1996

K963838

## **SAFETY AND EFFECTIVENESS SUMMARY - STARKEY TM**

**NAME OF DEVICE:** Starkey TM air conduction tinnitus masker.

**TYPE OF DEVICE:** Custom fit air conduction Tinnitus Masker -- Substantially equivalent to the Starkey CE-8 TML/TMC, K940667

**INTENDED USE:** To generate and transmit a pleasant white noise stimulus to aid in masking the user's tinnitus (or ringing in the ears)

**FEATURES:** Adjustable adjustable masker volume control, control for adjusting the masker frequency, color coding for left and right instruments.

**ASSEMBLY:** Assembled from standard components that are widely used in hearing aid devices throughout the industry.

**TECHNICAL CHARACTERISTICS:** Technical specifications comply with ANSI S3.22-1987

**FIT:** Frequency response varying based on the needs of the patient. Tolerances are maintained to a  $\pm 4$  dB range for SSPL

**CONTROLS:** Volume controls, similar to those used on other hearing aid devices. Potentiometers or switches may be incorporated as options require. Any pots or switches are similar to those used in other hearing aid devices.

**POWER:** Standard hearing aid battery, size 13 for ITE and size 312 for ITC

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